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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,672	08/10/2005	Franz-Georg Hanisch	50316/012001	3739

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

NOTIFICATION DATE	DELIVERY MODE
01/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/525,672	HANISCH, FRANZ-GEORG	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 25-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6 and 25-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus. In view of this Pietersz et al (Vaccine, 2000. 18:2059-2071; IDS – 02/24/2005) reads on the claim. Pietersz et al teach a peptide of 9 amino acids in length derived from the VNTR repeat region of MUC1 that comprises the amino acid sequence SAP at its N-terminus (please see page 2060 Table 1, fragment 229-237), Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, 25 and 51-58 are drawn to a peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

II. Claim 26 is drawn to a nucleic acid encoding a peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

III. Claims 27-30 are drawn to a method of producing a peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

IV. Claims 31 and 32 are drawn to a peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus obtained by providing a peptide comprising tandem repeat domain of MUC1 or a part thereof and contacting the peptide with an effective amount of cathepsin-L.

V. Claims 33-40 are drawn to an ex-vivo method of producing a population of autologous APCs, comprising providing autologous APCs from a tumor patient, contacting the autologous APCs from the tumor patient with an effective amount of a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

VI. Claims 41-48 are drawn to an ex-vivo method of producing genetically engineered APCs, comprising providing a nucleic acid encoding a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

VII. Claims 49 and 50 are drawn to an APC obtained by an ex-vivo method of producing genetically engineered APCs, comprising providing a nucleic acid encoding a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

VIII. Claims 59-67 are drawn to a method of treating a patient suffering from a MUC1-positive carcinoma, comprising administering a composition comprising a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Pietersz et al the groups are not so linked as to form a single

general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I, II, IV and VII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The peptide molecule of Group I, the nucleic acid molecule of Group II, the peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus obtained by providing a peptide comprising tandem repeat domain of MUC1 or a part thereof and contacting the peptide with an effective amount of cathepsin-L of Group IV and the APC obtained by an ex-vivo method of Group VII are all structurally and chemically different from each other. The peptide of Group I can be produced by linking amino acids via peptide bonds and can be used for antibody synthesis, the nucleic acid molecule of Group II is made by nucleic acid synthesis, while the peptide of Group IV is produced by providing a peptide comprising tandem repeat domain of MUC1 or a part thereof and contacting the peptide with an effective amount of cathepsin-L and can be used for diagnostic purposes and the APCs of Group VII are produced by an ex-vivo method, comprising providing a nucleic acid encoding a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus. Thus, the examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and

would require the consideration of different patentability issues. Thus the inventions I, II, III, VIII and IX are patentably distinct.

The inventions of Groups III, V, VI and VIII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Group III is drawn to a method of producing a a peptide of at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus, Group V is drawn to an ex-vivo method of producing a population of autologous APCs, comprising providing autologous APCs from a tumor patient, contacting the autologous APCs from the tumor patient with an effective amount of a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus, Group VI is drawn to an ex-vivo method of producing genetically engineered APCs, comprising providing a nucleic acid encoding a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus and Group VIII is drawn to a method of treating a patient suffering from a MUC1-positive carcinoma, comprising administering a composition comprising a peptide or fusion molecule comprising at least 9 amino acids in length derived from the tandem repeat domain of MUC1 and having the amino acid sequence SAP at its N terminus. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different

products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions IV-IX are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group I and the method of Groups III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the peptide product as claimed can be used in a materially different process such as antibody production in addition to the materially different method of Groups III and VIII.

The inventions of Group II and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic acid product as claimed can be used in a materially different

process such as hybridization assays in addition to the materially different method of Group VI.

The invention of Group VII and the methods of Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the antigen presenting cells as claimed can be used in a materially different process such as screening for specific T cell receptors in addition to the materially different method of Group V.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi
Ph: (571) 272-8789

DAVID J. BLANCHARD
~~PATENT~~ EXAMINER
PRIMARY